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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/003,047 01/05/98 VAN OUYEN A 261922003302

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HM12/0628

EXAMINER

ZAGHMOUT, O

ART UNIT

PAPER NUMBER

1649

DATE MAILED:

06/28/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/003,047

Applicant(s)
Van Ooyen et al.

Examiner
Ousama Zaghmout

Group Art Unit
1649



☒ Responsive to communication(s) filed on 5-27-1999, 6-7-1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 19-23, 27, 28, 33-36, 38, 39, 41, 42, 44, 47, 48, 50, 51, and 53 are pending in the application.

Of the above, claim(s) 19-23, 33-35, 38, 41, 44, 47, 50, and 53 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 27, 28, 36, 39, 42, 48, 51, and 54-58 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED OFFICE ACTION

The amendments filed 5-27-1999 [Paper No. 9] and 6-7-1999 [Paper No. 10] have been received and entered.

Claims 1, 19-23, 27, 28, 33-36, 38-39, 41-42, 44, 47-48, 50-51, 54-58 are pending. Claims 19-23, 33-35, 38, 41, 44, 47, 50, 53 stand withdrawn from consideration on the merit as they are drawn to a non-elected invention.

Claims 26, 45, 59-60 have been canceled. Claims 1, 27, 28, 36, 39, 42, 48, 54, 56, 58 have been amended.

The 1449 submitted 4-9- 1998 is noted. However, the copies of the references have not been recieved. They will be considered when filed.

Claim Rejections - 35 USC § 112

Ist. Paragraph

Claims 1, 27-28, 36, 39, 42, 48, 51, 54-58 remain rejected under 35 USC 112, first paragraph as being based upon a disclosure which is insufficient to permit those skilled in this art to practice the invention, for the reasons set forth for claims 1, 26-28, 36, 39, 42, 45, 48, 51, 54-58, at pages 3-6 of the previous Office action of 11-24-1999.

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Applicants' arguments filed 5-27-1999 [Paper No. 9] and 6-7-1999 [Paper No. 10] have been fully considered but not found persuasive.

The arguments set out in the Applicants' response, in brief, is that the rejection of claims 1, 26-28, 36, 39, 42, 45, 48, 51, 54-58 for lack of enablement should be withdrawn because Applicants have shown in the specification the expression in plants of two microbial enzymes, α -amylase and gluco-amylase, without modification of the coding sequence (Example 2 and 9). Based on that, Applicants conclude that the predictability is not at the levels which would discourage the skilled practitioner [paragraph 2, page 2, amendment of Paper No.10]. The Examiner respectfully disagrees for a number of reasons:

1. The nucleotide sequence which encodes glucanase protein is not the same as the nucleotide sequence which encodes α -amylase or gluco-amylase. There are many genes of microbial origins that need very extensive modification in the coding sequence for efficient plant expression. There are multiple sequence motifs that are not common in the coding region of plant genes are found to be common in many microbial nucleotide sequences. These include localized regions of A+T richness resembling plant introns, potential plant polyadenylation signal sequences, ATTTA sequences, which have been shown to destabilize mRNA in other systems, and codons rarely used in the plant. The instant disclosure does not disclose any step on how the mutagenesis, modification, the alteration of the coding sequence around the translation initiation site to accommodate Kozak consensus sequence. Furthermore, modification

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of the coding sequence to enhance the expression of non-plant gene in plants requires many steps which they have not be addressed in the instant disclosure which include: changes in the localization of the regions of A+T richness to resemble the plant introns, and the optimization of the potential plant polyadenylation signal sequences, ATTTA sequences to avoid any destabilization of the mRNA in the plant. Moreover, the use of promoters, fusion proteins, and leader sequences have not been shown to significantly increase the microbial protein gene expression. The Examiner would like to bring to the attention of the Applicants that the expression of a transgene does not depend only on the integration into the host genome, said transgene has to be activated which is then has to go through a number of steps such as the initiation of transcription, transcript process, transport to cytoplasm and translation of mRNA. As such, the obtention of a transgenic plant with a desirable phenotype is unpredictable. While Applicants may be able to obtain a transgenic plant that has a transgene, but this does not mean that the desirable trait will be obtained as discussed supra. Applicants have failed to address many of other important issues which are essential for the enablement of the invention as broadly claimed in the instant application. Applicants have provided no specific guidance as to how to select the nucleotide sequences or sub-nucleotide sequence which will produce a protein or a polypeptide to impair cellular function. One wishing to practice the invention is left to proceed through trial-and-error to see what will work and what will not. Hence, due to the lack of any working examples of the inventions, and the inability of one skilled in the art to predict which if any of all possible proteins which will be useful in the manner suggested,

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and the unpredictability of the field, it would require undue experimentation to practice the claims. Consequently, the rejection of claims 1, 26-28, 36, 39, 42, 45, 48, 51, 54-58 is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Ousama M-Faiz Zaghmout whose telephone number is (703) 308-9438. The Examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, L. Smith, can be reached on (703) 308-3909. The fax phone number for the group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to THE MATRIX CUSTOMER SERVICE CENTER whose telephone number is (703) 308-0196.

Ousama M-Faiz Zaghmout Ph.D.

June 19, 1999


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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